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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/731,521 | 12/09/2003 | Sudhir V. Shah | 2629.1003-010 | 3717 |

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EXAMINER

WINSTON, RANDALL O

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1654

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/731,521

Applicant(s)

SHAH, SUDHIR V.

Examiner

Randall Winston

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1203.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the term “essentially constant.” No objective criterion is provided in the specification or claim to apprise one of skill in the art of the meaning of “essentially constant.” Accordingly the metes and bounds of this term is not clearly delineated. (What does essentially mean?)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-7 and 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Green (US 4,684,482) as is evidenced by Martin et al. (US 6206849), Schwart (US 6383817), Ranganathan et. al (US 6706287), and Akbarov et al. (Derwent-Acc-No-2000-594407).

Applicant claims a method for administering orally an iron chelator to a human selected from the group consisting of deferiporone, deferoxamine, polyanionic amines

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and substituted polyaza compounds, whereas the iron chelator treats progressive kidney disease.

Green anticipates the claimed invention (see, e.g. column 3 lines 34-47, column 2 lines 3-5) because Green teaches a method of administering orally an iron chelator, such as deferoxamine, to the patient to treat kidney-damaged patients undergoing renal dialysis.

Martin et al. (US 6206849, see e.g., column 2 lines 24-29) teach that patients undergoing renal dialysis have kidney damage associated with end-stage progressive kidney disease. Therefore, deferoxamine would inherently halt the progression of the kidney disease and/or reduce the severity of the progressive kidney disease and/or reduce the rate of loss of renal function when administered to patients undergoing renal dialysis due to kidney damage associated with end stage kidney.

Regarding claim 11, Schwartz (see, e.g. column 10 lines 1-3) teaches that proteinurea is indicative of kidney damage and/or failure. Ranganathan et al. (see, e.g., column 7 lines 29-34) teach that an increase in serum creatinine is indicative of kidney failure and/or kidney damage (claims 12 and 14). In regard to claim 13, Akbarov et al. (see, e.g., abstract) teach that treating progressive kidney damage increases the glomerular filtration rate. Therefore, administration of deferoxamine to treat patients undergoing renal dialysis, as taught by Green, would inherently reduce the rate of progression of proteinurea, the rate of increase of serum creatinine and the rate of deterioration of glomerular filtration rate in these patients.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 5, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green in further view of Mita et al. (JP 405000949, see abstract)

Applicant claims a method for administering an iron chelator to a human in various amounts selected from the group consisting of deferiprone, deferoxamine, polyanionic amines and substituted polyaza compounds, whereas the iron chelator treats a progressive kidney disease selected from the group consisting of diabetic nephropathy, primary glomerulonephritis and secondary glomerulonephritis.

As outline supra, Green teaches administering orally an iron chelator, such as deferoxamine (see, e.g. title, column 2 lines 3-5), to kidney-damaged patients undergoing renal dialysis.

Green does not teach the administration of an iron chelator to a patient suffering from diabetic nephropathy, how the iron chelators are to administered, in what amounts they are to be administered or iron chelators other than deferoxamine.

Mita et al. teach (see, abstract) that diabetic nephropathy causes kidney failure and/or damage.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have administered an iron chelator to a patient suffering

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from diabetic nephropathy because Green's teaches administering an iron chelator to a patient with kidney damage and Mita et al. teach that diabetic nephropathy causes kidney failure and/or damage. Regarding specifically claimed routes of administration and dosages, the adjustment of conventional working conditions therein (e.g. how the iron chelator is administered and in what amounts), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Prior Art

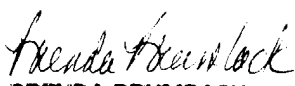
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Torti (US 6589966, see, e.g, column 2 lines 32-42) teaches that deferiprone is an iron chelator used for *in vivo* treatment.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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